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DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Dallas Division

United States of America
***ex rel.* Lewis Eastlick, M.D.**

Plaintiffs,

vs.

James W. Galbraith, M.D.
Defendant.

3-19CV-245-M

FILED UNDER SEAL

Pursuant to
31 U.S.C. § 3730(b)(2) & (3)

Jury Trial Demanded

COMPLAINT

1. *Qui tam* Plaintiff Lewis Eastlick, M.D., through his attorneys, brings this Complaint on behalf of the United States, and on his own behalf, pursuant to the federal False Claims Act, 31 U.S.C. § 3730 *et seq*.

2. Dr. Eastlick alleges that Dr. Galbraith submits medically unnecessary and unreasonable claims for reimbursement from the U.S. Government for:

- sacroiliac joint injections,
- anesthetic nerve injections,
- joint aspirations,
- bile duct diagnostic injections and x-rays, and
- other medically unnecessary and unreasonable procedures.

I. Jurisdiction, Venue, and Parties

3. This Court has jurisdiction under 31 U.S.C. § 3732 and 28 U.S.C. § 1345.

4. This Court has personal jurisdiction over Defendant because he transacts business and can be found in this district, and committed acts within this district that violate 31 U.S.C. § 3729 and 31 U.S.C. § 3732(a).

5. Upon information and belief, no jurisdictional bars apply. 31 U.S.C. § 3730(e).

6. Venue is proper in this district under 31 U.S.C. § 3732(a) and 28 U.S.C. §1391(b) and (c) because Defendant resides and/or transacts business in this district and has committed acts within this district that violate 31 U.S.C. § 3729.

7. Relator has complied with all procedural requirements of 31 U.S.C. §3730(b)(2).

8. **Relator / Qui Tam Plaintiff Lewis Eastlick, M.D.,** is Board Certified by American Board of Surgery in General Surgery-Hand Surgery and practices medicine in Florida. Relevant

to the allegations below, Dr. Eastlick uses anesthetic blocks with almost all surgeries, and anesthetic injections are part of his daily practice. In addition, Dr. Eastlick has had training in biliary (bile duct) imaging.

9. While Dr. Eastlick has significant evidence of the frauds alleged herein (the details of which follow), much of the documentary evidence necessary to prove the allegations in this Complaint is in the possession of Defendant and the United States. Based upon his knowledge, data, and personal experience, Dr. Eastlick has a reasoned factual basis to assert these allegations made upon information and belief.

10. **Defendant James Walter Galbraith, M.D., J.D.**, submits claims for Medicare payments under NPI 1366469926. The Texas Medical Board indicates that Dr. Galbraith has practiced medicine since 1974 under license E2567, holds no hospital privileges, does not participate in Medicaid, and shows his primary practice address in Dallas, Texas. Dr. Galbraith is also a lawyer and a member of the Texas bar, license 07574405, since 1992. The bar shows a "practice area: healthcare."

11. Defendant Galbraith is enrolled in and provides services to beneficiaries under the Medicare Program, which paid him the following amounts under Part B:

- 2014 $ 743,602
- 2015 1,076,057
- 2016 1,234,566

12. Dr. Galbraith is not Board certified in pain management, anesthesiology, rheumatology, orthopedic medicine, interventional radiology, diagnostic radiology, or surgery.

II. The False Claims Act and Medicare

13. The Federal False Claims Act prohibits the submission of false or fraudulent claims and false statements so as to obtain or keep federal money. It provides, in pertinent part:

> (1) In general.— Subject to paragraph (2), any person who—
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> * * *
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . ., plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

14. Under the False Claims Act, a private person may sue in federal district court for him/herself and for the United States and may share in any recovery. 31 U.S.C. § 3730(b). That private person is a *relator*, and the action that the relator brings is called a *qui tam* action.

15. Under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted from $ 5,500 to $ 11,000 for violations occurring on or after September 29, 1999. For violations that occurred after November 1, 2015, Department of Justice (DOJ) announced increased penalties to between $10,781 and $21,562 per fraudulent claim.[1]

16. Medicare, enacted in 1965 under Title XVIII of the Social Security Act, is a third-party reimbursement program that underwrites medical expenses of the elderly and the disabled. 42

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[1] https://www.federalregister.gov/documents/2017/02/03/2017-01306/civil-monetary-penalties-inflation-adjustment-for-2017

U.S.C.§§ 1395 *et seq*. Medicare reimbursements are paid from the federal Supplementary Medical Insurance Trust Fund.

17. Medicare Part B generally covers physician services, including medical and surgical treatment and outpatient treatment and diagnosis. Part B, 42 U.S.C. §§ 1395j *et seq*.; 42 U.S.C. §1395l (payment of benefits). The Medicare claims in this case arise under Medicare Part B.

18. Physicians must enroll in the Medicare program to be eligible to receive payment for covered services provided to program beneficiaries. 42 C.F.R. § 424.505.

19. CMS requires that all claims for physician services be submitted on a form CMS-1500 (Health Insurance Claim Form) ("Form 1500") or its electronic equivalent. 42 C.F.R. 424.32 (Basic requirements for all claims).

20. At all times relevant to this action, Defendant submitted, or caused to be submitted, the electronic equivalent of Form 1500 to CMS.

21. Form 1500 requires the submitting healthcare provider to include various fields of information prior to reimbursement, including: the date(s) of service; a code for the service(s) provided known as a "Current Procedural Terminology Code" or "CPT Code"); and the rendering healthcare provider's national identification number ("National Provider Identifier" or "NPI") and signature.

22. According to Form 1500's instructions, a provider's signature certifies "that services shown on [the Form 1500] were medically indicated and necessary for the health of the patient and were personally furnished by [the provider] or were furnished incident to [his/her] professional service by [his/her] employee under [his/her] immediate personal supervision."

23. Providers, such as Defendant, submit claims to Medicare by transmitting them to a private carrier or a Medicare Administrative Contractor ("MAC"), which processes the claims on behalf of HHS/CMS.

24. All healthcare providers that submit claims electronically to CMS or to CMS MACs, must certify in their application that they "will submit claims that are accurate, complete, and truthful," and must acknowledge that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *See* Medicare Claims Processing Manual, § 30.2.A.

25. Medicare permits reimbursement only for medical treatments which are "reasonable and necessary for the diagnosis and treatment of illness or injury . . .." 42 U.S.C. § 1395y(a)(1)(A). *See also* 42 C.F.R. § 411.15(k)(1). The Secretary may issue National Coverage Determinations to define what services are considered reasonable and necessary, and if there is no applicable national coverage determination, a Medicare contractor may issue a "local coverage determination" stating whether an item or service is covered within that contractor's juridiction. *Id.* § 1395ff(f)(2)(B). Where there is no applicable national or local coverage determination, Medicare contractors "make individual claim determinations . . . based on the individual's particular factual situation." 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). Nonetheless, procedures may be considered unreasonable or unnecessary even without a national coverage determination.

26. Courts have looked for guidance to the CMS Medicare Program Integrity Manual and its elucidation of what is "reasonable and necessary." The Manual includes at § 13.3 (incorporating § 13.5.1's definition of reasonable and necessary for individual claim determinations), among these definitional requirements, that the service is:

- Safe and effective;
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

27. Additionally, § 13.7.1 governs "Evidence Supporting LCDs." While § 13.3 does not specifically link to § 13.7.1, it looks to general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

- Scientific data or research studies published in peer-reviewed medical journals;
- Consensus of expert medical opinion (i.e., recognized authorities in the field); or
- Medical opinion derived from consultations with medical associations or other health care experts.

28. In addition to medical necessity and reasonableness, healthcare providers who submit claims to the Medicaid Program must certify, among other things, that all statements in the claim are true, accurate, and complete to the best of the provider's knowledge; that no material fact has been omitted; that the provider is bound by all rules, regulations, policies, standards, fee codes and procedures.

29. When submitting a claim for reimbursement, the claimant must provide documentation that supports the claim. Appropriate documentation typically involves correctly coding certain services to enable the Government to reimburse the healthcare provider at the proper rate.

30. "Upcoding" is an act of committing fraud by knowingly and intentionally submitting a claim under an inappropriate diagnostic or procedural code to obtain a higher rate of reimbursement.

31. Upcoding also occurs by changing the procedure code to a code that pays a higher rate of reimbursement.

32. Upcoding can harm patients medically and financially. Fabricated medical histories in patients' charts and medical records can forever skew diagnoses and treatment. This may cause a patient to undergo additional diagnostic exams or even cause a subsequent healthcare provider to perform a procedure that might be unnecessary were the patient viewed as lower risk. In addition, a patient may be declined or charged more for long-term care or life insurance due to these false diagnoses.

33. Under Medicare rules and policies, healthcare providers must contemporaneously create and maintain accurate medical records to support the providers' claims for reimbursement. *See e.g.,* CMS MLN Matters Number: SE1022 ("Providers/suppliers should maintain a medical record for each Medicare beneficiary that is their patient. Remember that medical records must be accurately written, promptly completed, accessible, properly filed and retained.")

III. False Claims for Unnecessary Injections and Aspiration

34. The claims Dr. Galbraith submits to Medicare reflect a pattern in which patients return with excessive frequency for unnecessary and potentially risky injections and aspirations (injecting or removing fluids). Dr. Eastlick alleges that this pattern indicates that Dr. Galbraith is claiming medically unnecessary treatments that result in the fraudulent submission of claims to Medicare.

35. Dr. Galbraith injects or aspirates his patients' nerves (CPT 64450), bile ducts (47531), and joints (CPT 20110), including knees (CPTs J7321, J7324, J7325) and sacroiliac (lower back) (27096).

36. Unnecessarily inserting needles to inject medications or remove or inject fluids risks patient harm. These risks include:

- Temporary and permanent nerve damage from hitting a nerve. For example, sciatic nerve damage can lead to lower limb paralysis.
- Puncture of a blood vessel (intravascular injection). Consequences can include: tinnitus, blurred vision, dizziness, tongue parathesias, and circumoral numbness or cardiac arrest.
- Infections around the injection location. Bacterial infection may cause cellulitis (subcutaneous fatty tissue inflammation) or abscesses.
- Adverse reactions to injected medications, such as a possible allergic reactions. Steroidal injections can risk harm by causing tendon rupture, skin discoloration, or allergic reactions.

37. Injected medications may also have side effects, and repeat injections increase the likelihood of side effects. Defendant's injections include anesthetics, anti-inflammatory medications (such as corticosteroids), and contrast dyes.

38. Side effects of steroids can include weight gain, increase in blood sugar in diabetics, water retention, and suppression of the body's own natural production of cortisone. This is even more of a risk for elderly patients on blood-thinning medications, with active infections, or with poorly controlled diabetes or heart disease.

39. Contrast dyes (radiocontrast media) are used to improve the visibility of internal organs and structures in X-ray based imaging techniques. They may have side effects ranging from itching to a life-threatening emergency, known as contrast-induced nephropathy (CIN). "The risk of CIN is dose-dependent" and the risk is higher for the elderly because of "age-related changes in renal function and the presence of old vessels, [and] coronary artery disease."[2] Contrast media may also lead to kidney dysfunction, especially in patients with preexisting renal impairment and in those with diabetes. *Id.*

40. Anesthetic's toxic effects can be local or systemic. Local toxic effects include prolonged anesthesia and paresthesia (an abnormal tingling, pricking, chilling, burning, or numb sensation) which may become irreversible. Systemic toxicity often involves the central nervous system or the cardiovascular system and may cause death or permanent brain dysfunction. Anesthetic agents can be toxic if administered inappropriately and, occasionally, even when properly administered.

A. Sacroiliac joint injections (CPT 27096) false claims

41. Sacroiliac ("SI") joint dysfunction generally refers to pain caused by abnormal motion (too much or too little) in the SI joint which, in turn, results in inflammation of the joint (sacroiliitis).

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[2] https://www.hindawi.com/journals/bmri/2014/741018/

42. SI joint injection is used primarily to diagnose or to treat low-back pain:

- Diagnostic: SI joint injection is used to confirm a suspected diagnosis of sacroiliac joint dysfunction. A local anesthetic (usually lidocaine or bupivacaine) typically is injected into the joint, with the goal of determining immediate pain relief to confirm the SI joint as the pain's source.
- Pain Relief: A therapeutic SI joint injection is done to provide relief of the pain associated with sacroiliac joint dysfunction. An anti-inflammatory medication (usually a corticosteroid) may help reduce inflammation within the joint, which is intended to alleviate the pain over time (typically, for several months, up to a year).

https://www.aapc.com/blog/26649-straight-up-coding-for-sacroiliac-joint-injections/

43. SI injections are usually performed in an operating or dedicated procedure room. The patient lies face down on his or her stomach on the radiography table. An intravenous line may be inserted to deliver medication provide sedation for the patient. The patient's vital signs (e.g., pulse rate and blood pressure) are monitored throughout the procedure.

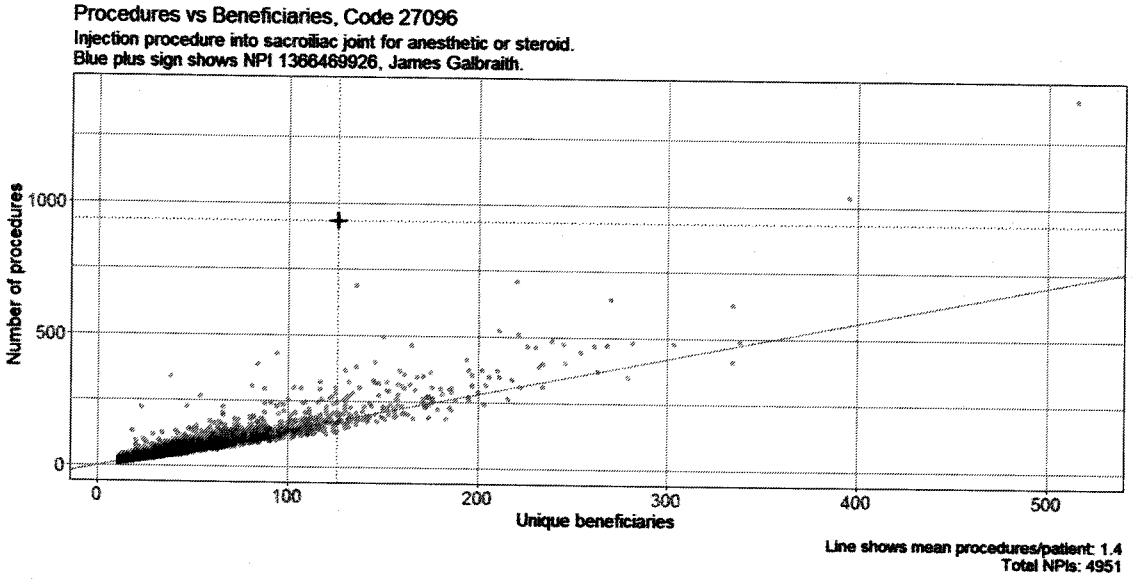
44. In Dr. Eastlick's experience, it could be medically necessary for a patient to receive at most two or three injections, usually two to three weeks apart. Rarely are more injections justified. If the initial injections are not efficacious then more would be medically unreasonable and unnecessary.

45. Practice standards both in Texas and throughout the U.S. demonstrate that Dr. Galbraith's frequent administration of more than three CPT 27096 SI join injections is inappropriate. Medicare part B claims nationwide reflect an average of about 1.5 claims per patient. This means that these practitioners typically perform this procedure once on about half of their patients and twice on the rest.

46. Unlike other practitioners in Texas and nearly 5,000 practitioners throughout the United States who claim this procedure approximately 1.5 times per patient, Dr. Galbraith averages more than *seven* claims per patient.

Procedure 27096 SI joint injections

year	total payment	total claims	total patients	avg. claims per patient
2014	$ 87,171	719	98	7.3
2015	120,323	1,006	134	7.5
2016	97,818	935	126	7.4
	$ 305,312	2,660		

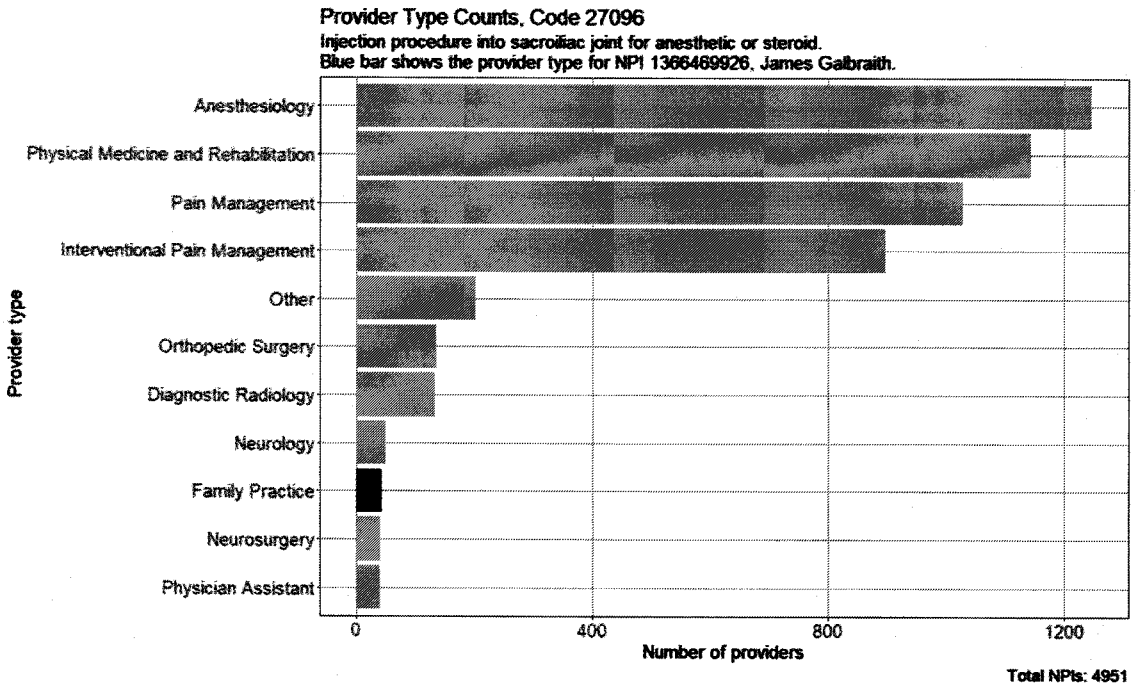


47. Dr. Galbraith claimed this procedure *more often than any doctor in Texas*, and more than almost any other doctor in the country, ranking from first to fourth in the number of paid procedures by Medicare part B.

27096 National Rank

year	claims rank	payment rank
2014	4	7
2015	1	2
2016	3	2

48. Unnecessary joint injections risk harm. For this reason, practitioners without board certification or specialized training, such as Dr. Galbraith, infrequently perform this procedure relative to specialists such as anesthesiologists, physical medicine, and rehabilitation physicians, orthopedic surgeons, and pain management specialists.



49. With respect to the CPT 27096's customary practices and standards of care in Texas, Relator concluded there was no "cluster" of symptoms or diagnoses in his locale that would indicate Defendant Galbraith's volume of repeat procedures are medically reasonable or necessary. The totality of Texas Medicare part B claims for this procedure support Relator's conclusion.

50. Because of this, many or most of Defendant's CPT 27096 claims are false.

B. Anesthetic nerve injection false claims (CPT 64450)

51. CPT 64450 is "injection of anesthetic agent, other peripheral nerve or branch." LCD 35222 describes the procedure:

> Nerve blocks cause the temporary interruption of conduction of impulses in PERIPHERAL nerves or nerve trunks by the injection of local anesthetic solutions.
>
> The use of nerve blocks or injections for the treatment of multiple neuropathies or PERIPHERAL neuropathies caused by underlying systemic diseases is not considered medically necessary. Medical management using systemic medications is clinically indicated for the treatment of these conditions.

> ...
>
> The use of ultrasound guidance in conjunction with these non -covered injections is also considered not medically necessary and will result in denial. Subcutaneous injections do not involve the structures described by CPT code 64450, direct injection into other PERIPHERAL nerves, but rather the injection of tissue surrounding a specific focus. These therapies are not to be coded using CPT code 64450. This code addresses the additional work of an injection of an anesthetic agent (nerve block), into relatively more difficult PERIPHERAL nerves, rather than that involved in an injection of relatively easily localized areas.
>
> ...
>
> *Utilization Guidelines*: Treatment protocols utilizing multiple injections per day on multiple days per week for the treatment of multiple neuropathies or PERIPHERAL neuropathies caused by underlying systemic diseases are not considered medically necessary.

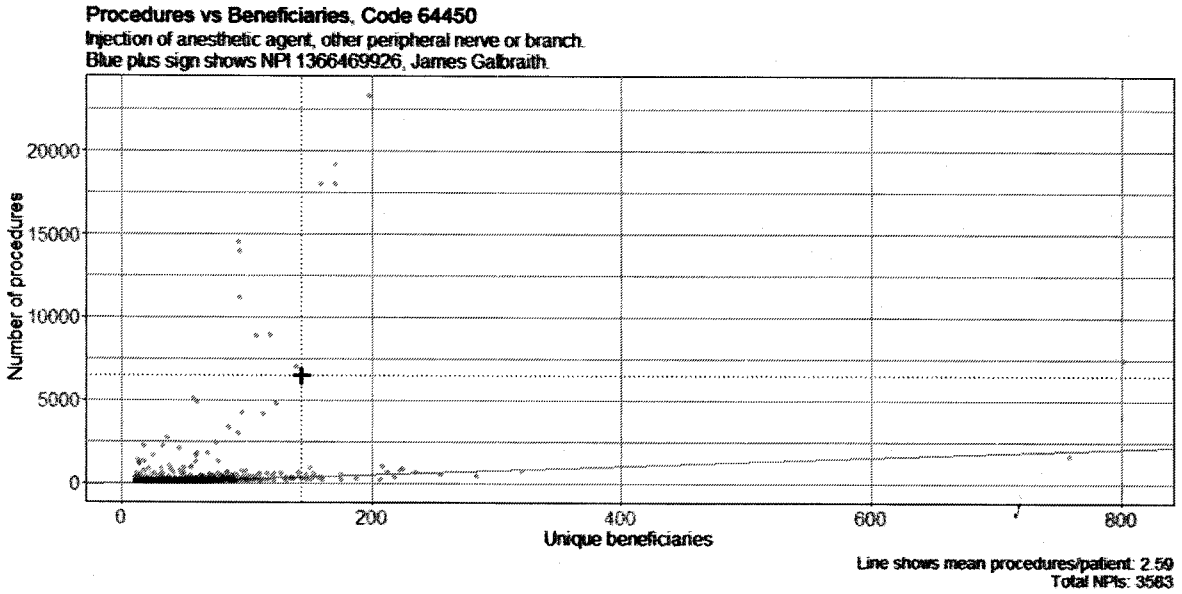
LCD 35222. [3]

52. Dr. Galbraith files excessive *claims per patient* for injections of nerve blocks. National and Texas practice standards, as reflected in Medicare part B payments, average about three claims per patient for this procedure. Dr. Galbraith's average number of claims per patient increased yearly from 13 claims per patient in 2014, to 39 per patient in 2015 and 45 per patient in 2016.

Procedure 64450 Injection of Nerve Block

year	total payment	total claims	total patients	Gailbraith claims per patient
2014	$ 26,904	728	56	13
2015	245,165	5,270	134	39
2016	361,920	6,462	144	45
	$ 633,989	12,460		

[3] LCD 35222 covers 48 states and Texas under Medicare part A, but no LCD covers Texas Medicare part B. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35222&ver=16&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=Texas&CptHcpcsCode=64450&bc=gAAAACAAAAAA&.



53. As discussed above, multiple injections risk patient harm in many ways, including nerve damage, infection, reaction to medication, broken needles, among others.

54. Because Dr. Galbraith is not Board certified in pain management or anesthesiology, his practice would not attract a patient population requiring treatments so far outside the norm.

55. By performing more and more procedures per patient, Dr. Galbraith increased his national rank for CPT 64450 Medicare part B revenue from 121st in 2014 to number eight in the United States in 2016 (and *number one in Texas*).

64450 National **Rank**

year	claims rank	payment rank
2014	117	121
2015	13	**11**
2016	12	**8**

56. The sheer number of nerve blocks performed by Dr. Galbraith indicates that a substantial number of the nerve blocks were medically unnecessary and unreasonable.

57. For this reason, Dr. Eastlick alleges that many or most the claims submitted by Dr. Galbraith for CPT 64450 are false.

C. Joint aspiration (CPT 20610) false claims

58. CPT 20610 is "Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); without ultrasound guidance." A coding website explains more fully:

> CPT® 20610 describes aspiration (removal of fluid) from, or injection into, a major joint (defined as a shoulder, hip, knee, or subacromial bursa), or both aspiration and injection of the same joint. The procedure may be performed for diagnostic analysis and/or to relieve pain and swelling in the joint.
>
> ...
>
> These procedures are distinct from aspiration or injection of a ganglion cyst (20612 Aspiration and/or injection of ganglion cyst(s) any location) and sacroiliac (SI) joint injection without image guidance (20552 Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)).
>
> Effective for claims with dates of service on or after Jan. 1, 2015, you may no longer report image guidance separately with 20600, 20605, or 20610. Instead, you would report 20604, 20606, or 20611, as appropriate.
>
> *Report only a single unit of 20610 for each joint treated, regardless of how many aspirations and/or injections occur in a single joint. For example, if the physician administers two injections, one on either side of the right knee, you would report 20610 x 1.* The Centers for Medicare & Medicaid Services (CMS) instructs that you should also "Indicate which knee was injected by using the RT (right) or LT (left) modifier (FAO-10 electronically) on the injection procedure (CPT® 20610)."

https://www.aapc.com/blog/27495-problem-code-20610/ [emphasis added.]

> A physician shall not report more than one (1) UOS for arthrocentesis of any one joint regardless of whether or not the physician also aspirates or injects one or more of its surrounding bursae. For example, if a physician performs arthrocentesis of the shoulder and two bursae of the same shoulder without ultrasound guidance, only 1 UOS of CPT code 20610 may be reported.

CMS National Correct Coding Initiative, Ch, 9 final1 0312018 [emphasis supplied]. [4]

59. National claim volume for Medicare part B CPT 20610 is approximately 1.8 times per patient (or for 10 typical patients, eight have two claims, and two have only one).[5] In Texas,

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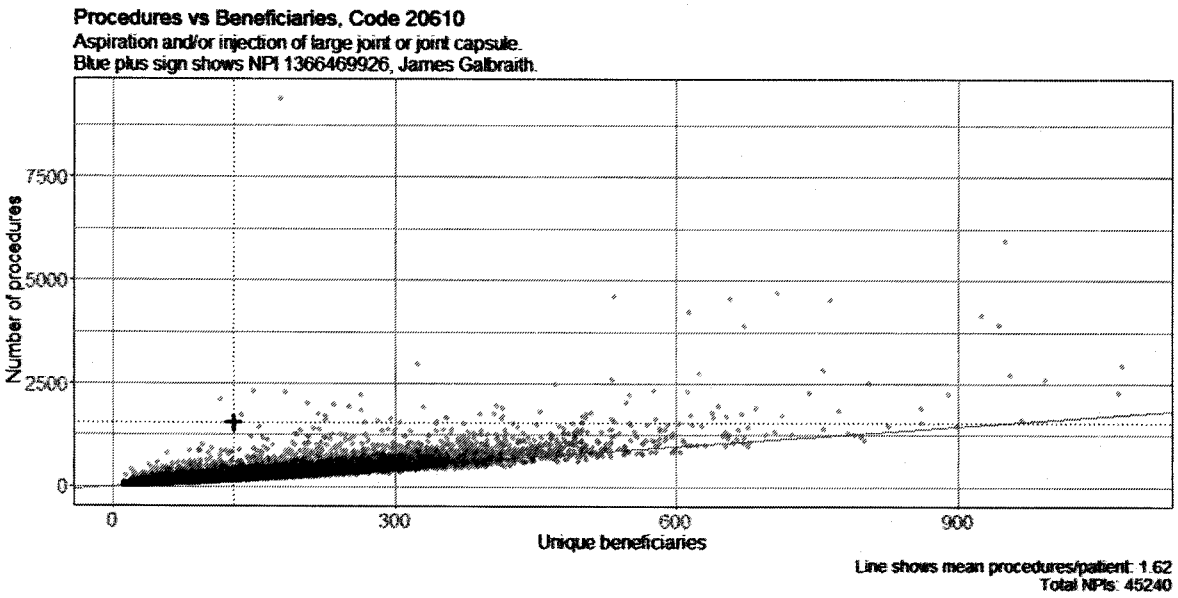
[4] https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html

practice standards indicate slightly fewer claims per patient, only 1.7. Significantly, CMS has paid Dr. Galbraith for this procedure, on average, ten to 12 times per patient.

Procedure 20610 Aspiration and/or injection of large joint or joint capsule

year	total payment	total claims	total patients	avg. claims per patient
2014	$ 48,063	1,063	107	9.9
2015	56,659	1,258	121	10.4
2016	63,182	1,538	128	12.0
	$ 167,904	3,859		

60. As illustrated below, even though many others perform the procedure on more patients, Dr. Galbraith again stands far from the practice standards in his repetitions per patient.



61. The above chart likely *understates* Dr. Galbraith's repeated claims per patient because it does not identify patients who received one or more of these procedures the preceding year or the following year.

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[5] Based on 2016 total part B line service count of 5,471,150 for 3,021,810 unique patients.

62. As noted above, the procedure involves removing fluid for diagnostic purposes or for comfort. There is no medical reason to continually repeat the procedure for a diagnosis. This is because lab results may allow the physician to prescribe a medication.

63. When the procedure is performed for symptom relief, a frequency of 10 times per patient is medically unreasonable and unnecessary. If the patient does not improve, then the patient is typically referred to a specialist, such as an orthopedic surgeon, and does not return to the practitioner for additional aspirations.

64. Because Dr. Galbraith is not Board certified in these relevant specialties, he would not be a physician that would attract referrals of patients with significant orthopedic problems that would require this procedure to be performed with such excessive frequency.

65. With respect to the medical necessity for CPT 20610 and customary practices in and around Texas, Dr. Eastlick concluded that:

- There is no "cluster" of symptoms or diagnoses that would suggest Defendant Galbraith's volume of repeat procedures are medically reasonable or necessary.
- It is medically unreasonable and inappropriate to repeatedly aspirate and/or inject large joints on this many patients.

66. Other physicians' Medicare part B claims confirm that accepted standards of medical practice in Texas and throughout the United States are consistent with Dr. Eastlick's experience and conclusions.

67. For the reasons above, many or most of the CPT 20610 claims Defendant Galbraith submitted for payment to Medicare for CPT 20610 are false.

D. Bile duct diagnostic injections and x-rays (CPT 47531) false claims

68. CMS defines CPT 47531 as

> Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access.

69. Medical professionals call this "percutaneous transhepatic cholangiography" (PTC). In lay terms, it involves injecting contrast material directly into the bile ducts, and then producing x-ray images of the bile ducts. Bile is a fluid that aids in digestion, and bile ducts carry bile from the liver and gall bladder.

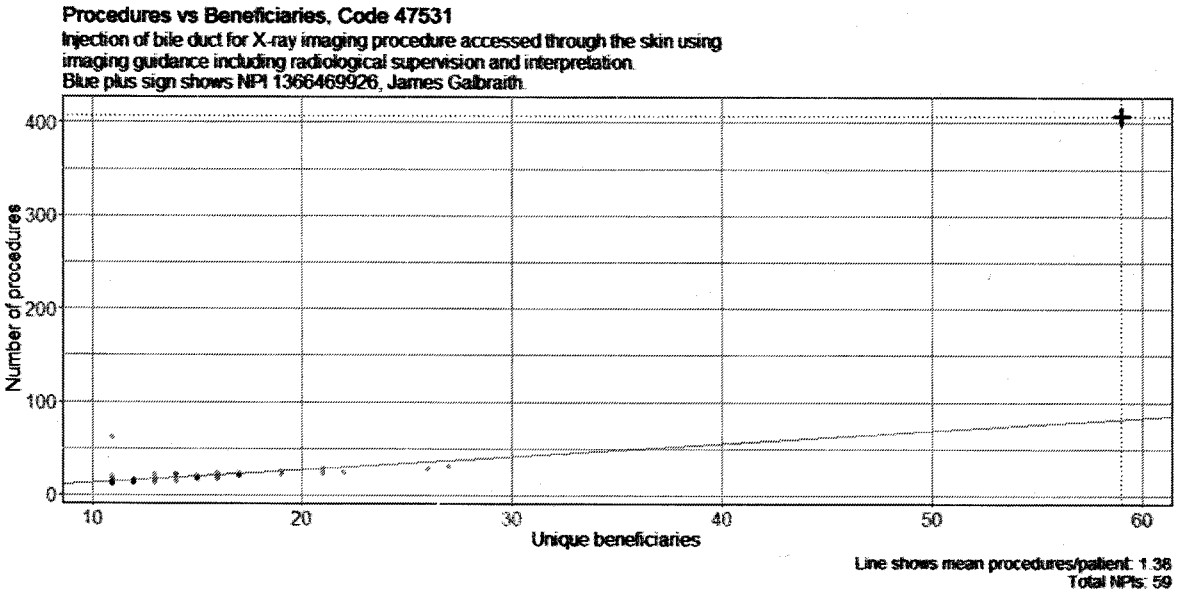
70. This diagnostic imaging is designed to identify abnormalities in the bile ducts such as a block, narrowing or dilation (widening), and it is one approach to diagnosing bile duct cancer.

71. Bile ducts are usually diagnosed and treated by trained experts such as an interventional radiologist, diagnostic radiologist, gastroenterologist, or a surgeon. Typically, the procedure is performed in an imaging facility.

72. Although there are few indications for bile duct injections, less invasive modalities for imaging the biliary tree may be safer for the patient. Such options include gastroenterologic / radiologic supervision, and interpretation of endoscopic catheter insertion (CPT 74328), and related procedures under CPT codes 47531 – 47999 and 74363.

73. Dr. Galbraith lacks board certifications indicating the training to determine whether this potentially dangerous diagnostic procedure is medically reasonable or necessary.

74. Dr. Galbraith's CPT 47531 reimbursements for 2016 ranked him *the highest Part B biller nationwide* for this procedure, for which Medicare reimbursed him for 107 claims for 59 patients, averaging 6.9 per patient. In contrast, the rest of the country averages less than twice per patient.



75. Defendant Galbraith performs no other procedures typical of patients who would require such an invasive diagnostic (such as CPTs 47531 – 47999).

76. Dr. Eastlick's investigation has determined that Defendant Galbraith's reputation in the professional community would not have brought about referrals of patients requiring this diagnostic procedure. This is because Defendant Galbraith is not an interventional radiologist, diagnostic radiologist, or a surgeon.

77. If Defendant Galbraith actually performed these invasive diagnostics, then he unnecessarily punctured patients, unnecessarily inserted contrast materials into patients, and unnecessarily x-rayed patients – all of which risk patient harm.

78. For the reasons above, many or all of the claims Dr. Galbraith submitted to Medicare for CPT 47531 claims are false.

E. Ultrasonic guidance imaging supervision (CPT 76942) false claims

79. Ultrasound guidance imaging helps place needles deep within a patient at a site that is not visible. For example, ultrasonic guidance would be necessary in a hospital to remove fluid from a lung or a deep cyst that cannot be located visually. However, if there is fluid in a knee, a physician does not require ultrasonic guidance to find a knee cap or the space beneath it.

80. There exist few indications for using ultrasound guidance. CMS National Correct Coding Initiative, Ch. 9 final10312018.[6] This would be especially so for Defendant Galbraith, who would not be referred patients with problems deep within the body.

81. The use of ultrasound guidance in conjunction with non-covered CPT 54450 injections (or any unnecessary injection) would also be considered not medically necessary. *See* LCD L35333 (unnecessary nerve blocks cannot justify unnecessary guidance).[7]

82. Dr. Galbraith claims per patient far exceed the national average of 1.3 procedures per patient; and the Texas average of 1.4 per patient.

Procedure 76942 Ultrasound Guidance

year	total payment	total claims	total patients	Gailbraith claims per patient
2014	$ 94,086	1,734	102	17
2015	42,630	950	113	8
2016	59,096	1,344	114	12
	$ 195,812	4,028		

83. In contrast to all other 2016 Part B average claims per patient of 1.3, Dr. Galbraith averaged 17 per patient in 2014, 8 in 2015 and 12 in 2016.

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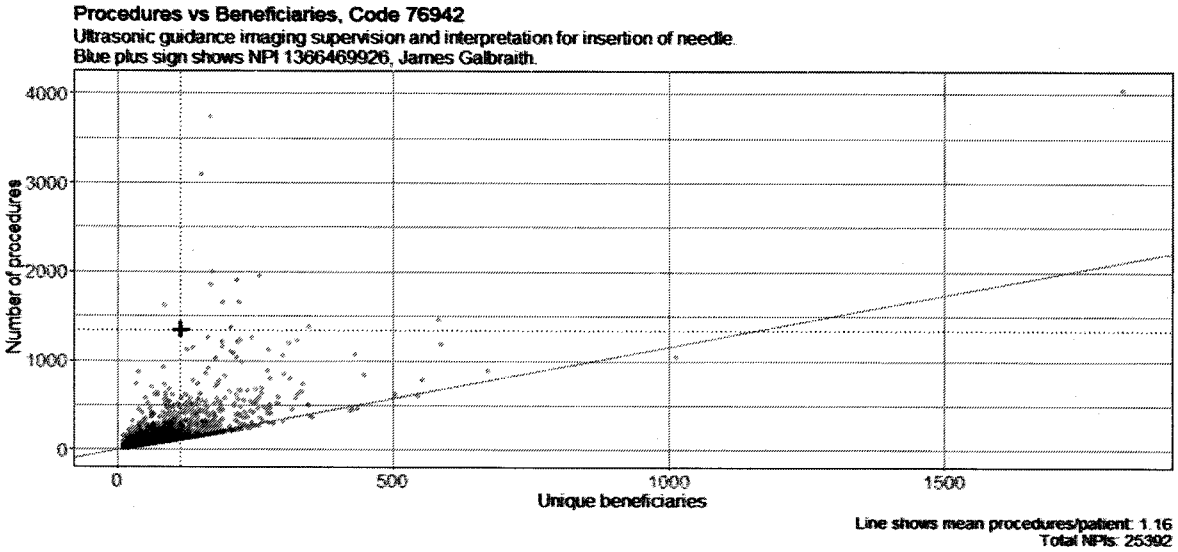
[6] https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html

[7] https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35222&ver=13&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCD&PolicyType=Final&s=51&KeyWord=peripheral&KeyWordLookUp=Doc&KeyWordSearchType=Exact&CptHcpcsCode=64450&kq=true&bc=IAAAACAAAAAA&



84. For the reasons above, many or most of the claims Defendant Galbraith's has submitted for payment to Medicare for CPT 76942 claims are false.

IV. Counts I – II

A. Count I: Violations of 31 U.S.C. § 3729(a)(1)(A)

Plaintiff repeats and realleges the preceding paragraphs above as if fully set forth herein.

85. Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to Government Health Care Programs, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

86. The United States paid said claims and has sustained damages because of these acts by the Defendants.

B. Count II: Violations of 31 U.S.C. § 3729(a)(1)(B)

Plaintiff repeats and realleges the preceding as if fully set forth herein.

87. Defendant knowingly made, used or caused to be made, or used false records or statements material to a false or fraudulent claim, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

88. The United States paid said claims and has sustained damages because of these acts by Defendant.

PRAYER

WHEREFORE, *Qui Tam* Plaintiff Relator, for the United States and for himself, prays that judgment be entered against Defendant as follows:

A. For each count, the amount of damages, trebled as required by law, and civil penalties up to the maximum permitted by law,

B. For the maximum *qui tam* percentage share allowed by law,

C. For attorney's fees, costs and reasonable expenses; and

D. For any and all other relief to which Plaintiffs may be entitled.

Plaintiff requests trial by jury.

Mitchell R. Kreindler,
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7676 Hillmont St Suite 240A
Houston TX 77024
Texas Bar No. 24033516
713.647.8888
mkreindler@blowthewhistle.com

Jonathan Kroner
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Miami, Florida 33131
305.310.6046
jk@FloridaFalseClaim.com

Attorneys for *Qui Tam* Plaintiff Relator

JS 44 (Rev. 06/17) - TXND (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States ex rel. [UNDER SEAL]

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Mitchell R. Kreindler, Kreindler & Associates, 7676 Hillmont Street, Ste 240A, Houston, TX 77040; 713.647.8888

DEFENDANTS

[UNDER SEAL]

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

3-19CV-245-L M

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☒ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
31 USC 3729. et seq.

Brief description of cause:
Qui tam action seeking recovery for false claims submitted to government

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
01/30/2019

SIGNATURE OF ATTORNEY OF RECORD
Mitch Kr

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

KREINDLER & ASSOCIATES

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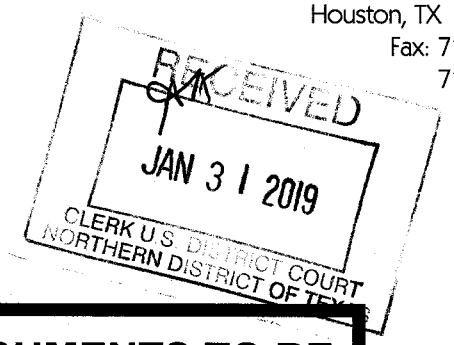
www.blowthewhistle.com

7676 Hillmont Street, Ste 240A
Houston, TX 77040-6478
Fax: 713.647.8889
713.647.8888



January 30, 2019

VIA OVERNIGHT DELIVERY

DOCUMENTS TO BE FILED UNDER SEAL

Ms. Karen S. Mitchell
Clerk of Court
U.S. District Court for the
Northern District of Texas
1100 Commerce Street, Room 1452
Dallas, TX 75242

Re: United States *ex rel.* [UNDER SEAL] *v.* [UNDER SEAL]
(N.D. Tex.)

Dear Ms. Mitchell:

Pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729(b)(2), *et seq.*, and Local Rules 3.2 and 79.3.a., I am enclosing for filing ***in camera* and under seal** a new civil action, including the original and one copy of following documents:

(1) Civil Cover Sheet;
(2) Complaint;
(3) Qui Tam Relator's Motion for Temporary Waiver of LR 83.10.a and proposed Order; and
(4) Certificate of Interested Parties.

In addition, please return to me file-stamped copies of the cover pages from the Complaint, Civil Cover Sheet and Motion. A self-addressed envelope and extra copies of those pages are enclosed for that purpose.

All documents are enclosed in a sealed envelope. Also enclosed is our firm's check for $400 to cover the cost of the filing.

Thank you for your assistance.

Sincerely,

Mitchell R. Kreindler

Enclosures